



Federal Drug Discount and Compliance Monitor

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The Inside Source on the Public Health Service 340B Drug Discount Program

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AMP Lawsuit Has Unintended Consequences *OPA's Halt in Pricing Verification Services Remains*

Frustration continues to mount in the 340B community after the Bush administration declined to appeal a U.S. District Court decision last month that temporarily blocks the government from redefining average manufacturer price (AMP) for prescription drugs. The Office of Pharmacy Affairs (OPA), which oversees the 340B program, has taken what some stakeholders argue are unnecessary precautions in lieu of the case.

Without an appeal, the preliminary injunction order—which prohibits the Department of Health and Human Services (HHS) from implementing a provision in the Deficit Reduction Act of 2005 (DRA) that would redefine AMP and prevents the Centers for Medicaid and Medicare (CMS) from posting data on the Internet related to the AMP for pharmaceuticals—will now remain in place indefinitely.

340B covered entities and advocacy groups are concerned because the Office of Pharmacy Affairs (OPA) has said it believes the ruling prevents the agency from responding to requests for help by covered entities wondering if they have been overcharged for a pharmaceutical product. OPA has advised covered entities to contact their wholesalers and drug companies to resolve any discrepancies.

"The longer the delay, the longer it is going to take us to recover overcharges,"

says Andrew Lowe, Director of Pharmacy at Arrowhead Regional Medical Center in Colton, Calif.

The agency has also temporarily halted the 340B Pricing Pilot—under which participating drug manufacturers provide pricing data to the 340B Prime Vendor Program (PVP) for comparison against the government's calculations. Any discrepancies between OPA and manufacturer calculations are then reconciled before a master price file is distributed to wholesalers participating in the PVP.

However, as long as the injunction remains in place, OPA will not be performing price comparisons or discussing anything related to AMP or pricing, according to OPA Director Jim Mitchell.

"I'm very disappointed that the pilot project, which is the best way for us to get pricing transparency, is getting caught up in whatever the issues are," says Marcus Farbstein, the Director of Government Affairs at Genentech, who first suggested the need for a pilot project at a 340B Coalition Conference. "I feel strongly that the pilot program is terribly important for program integrity."

The price transparency pilot was implemented following a series of reports on the 340B program from the Health and

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“Medicine for People in Need” Closes Its Doors

Funding Issues Prompt California-Based Organization to Suspend Operations

An advocate for safety net providers and an influential presence in the 340B community has closed its doors due to funding challenges. But although Medicine for People in Need (Medpin) ended its active program in December 2007 after eight years of service, “Its work lives on,” says Program Director Kathryn Saenz Duke.

Through training and education, technical assistance, policy analysis, and research, Medpin has worked with safety net providers for nearly a decade to improve access to medicine and pharmaceutical care for indigent patients in California and across the U.S. Medpin was a strong supporter of the 340B program and a valuable resource for bringing providers into the program and advising them on related pharmacy issues.

Started in 1999, Medpin was originally a project of a settlement agreement for a legal action brought by private parties under California anti-trust laws against many major drug companies. The project created a “financial and programmatic base” for the organization, according to Duke.

As part of the settlement, Medpin worked with all the parties to distribute more than \$170 million dollars worth of brand name drugs from 23 companies, at no charge to low-income recipients in California. As a result, drugs shipped to more than 100 safety net providers allowed them to fill 2.6 million one-month prescriptions for indigent patients, Duke says.

In the following years, however, Medpin was unable to find another “financial and programmatic base” to support its expanding scope of services. According to Duke, Medpin suffered the fate of most nonprofit organizations that rely primarily on philanthropic funding.

“We regret closing down now, but I’m proud of what we and our partners have accomplished over eight years,” she says. “Many of the organizations we partnered with

are continuing, and because some of them do similar work, we chose not to compete with them for funding.”

Nonetheless, Duke says Medpin was able to affect real changes among California’s safety net providers—particularly the state’s health clinics. As a result of Medpin’s technical assistance, which ranged from developing written materials to conducting local training workshops plus on-site assistance, providers throughout the state learned how to increase their effective use of patient assistance programs

(PAPs), better utilize the 340B program, and get high value from generic drugs.

“The end of Medpin will be a great loss to clinics, says Adrienne Villar, Pharmacy Associate at the Community Clinic Association of Los Angeles County. “They provided a lot of services that we as an organization don’t provide.”

As part of another litigation settlement project with

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Director Kathryn Saenz Duke

<p>THE MONITOR</p> <p>MANAGING EDITOR Katie O’Dowd</p> <p>SUPERVISING EDITORS Ted Slafsky William von Oehsen</p> <p>CONTRIBUTING WRITER Tom Mirga</p>	<p>The <i>Federal Drug Discount and Compliance Monitor</i> is a national monthly newsletter that covers the legal and political issues surrounding the Public Health Service 340B drug discount program and other developments in federal drug pricing law and policy. <i>The Monitor</i> also updates subscribers on breaking news stories through e-mail alerts.</p> <p><i>The Monitor</i> is published by Safety Net Hospitals for Pharmaceutical Access, a Washington D.C.-based trade association representing over 400 hospitals in the 340B program.</p> <p style="text-align: center;">Federal Drug Discount and Compliance Monitor 1501 M. Street, NW Washington, DC 20005 Phone: (202) 552-5853 Fax: (202) 552-5868 www.drugdiscountmonitor.com</p> <p>For information on <i>The Monitor</i>, including advertising opportunities, contact Katie O’Dowd at katie.odowd@drugdiscountmonitor.com or (202) 552-5853.</p>
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Merck Settlement Sheds Light on Whistleblower Law

In the wake of the recent high-profile Merck settlement, Congress is focusing renewed attention on government whistleblower cases. These cases, which involve allegations of fraud against government contractors, can lead to huge settlements between pharmaceutical companies and the government, resulting in tens of millions of dollars to the whistleblower and hundreds of millions in refunds to the federal and state governments.

While the suits filed under the False Claims Act (FCA) can focus on various areas of government corruption, including cases against defense contractors, many involve drug companies that have been accused of overcharging government health care programs. Several recent whistleblower suits have resulted in significant refunds to the 340B and Medicaid programs, including over \$9 million in refunds to 340B entities from the recent Merck settlement (See February's *Monitor*).

Sen. Charles Grassley (R-Iowa) faced off against the Department of Justice (DOJ) in a hearing last month about legislation he proposed that could have implications for both manufacturers and 340B providers. Grassley has been active on oversight issues related to the 340B program and has sent a number of letters to Department of Health and Human Services' Secretary Michael Leavitt and other government officials urging better oversight over the 340B program, particularly related to alleged overcharges by pharmaceutical manufacturers.

Grassley, who also co-authored the 1986 "qui tam" amendments to the FCA, and Sen. Richard Durbin (D-Ill.) introduced legislation (S.2041) last fall in response to court decisions that threatened to limit the scope of the FCA. The DOJ has since raised concerns about the legislation, which includes an amendment that would allow federal workers to sue and recover a portion of the proceeds themselves.

"The courts have done their best to undo the most effective tool of the federal government in rooting out fraud and abuse," Grassley said in a statement. "Our bill works to make sure recent court decisions won't weaken the government's ability to recover taxpayer dollars lost to fraud, whether it's in health care, defense or another area of spending."



Sen. Charles Grassley (R-Iowa)

The FCA allows a private citizen with knowledge of fraud against the government—called the *qui tam* plaintiff—to file a lawsuit on behalf of the government against the person or business that committed the fraud. Pleadings and judicial orders in *qui tam* cases are generally kept under seal to prevent them from being made a matter of public record while the DOJ investigates and determines whether it will prosecute the claims.

"These amendments have been highly successful in helping the Department of Justice prosecute individuals and corporations that have defrauded the Government," Grassley said in a statement. "But, they haven't done it alone. Courageous whistleblowers have been there almost every step of the way."

The recent allegations against Merck were brought in two separate lawsuits filed by whistleblowers under the FCA. On February 7, Merck agreed to pay \$671 million to resolve allegations that from 1998 through 2006 the company engaged in illegal marketing activities and submitted false price reports to the government in order to reduce the rebates it owed to Medicaid. Whistleblower H. Dean Steinke will receive \$68 million. The amount owed to whistleblower William St. John LaCorte has yet to be finalized. The Merck settlement pushed the total recovery from the FCA to over \$20 billion for the government since 1986, according to Grassley.

Patrick Burns, Director of Communications for Taxpayers Against Fraud, a nonprofit organization dedicated to protecting the FCA, says the government only joins approximately 100 False Claims lawsuits a year. The DOJ is currently reviewing 630 health care whistleblower claims.

At the February 27 hearing, Grassley, along with both Democratic and Republican members of the Senate Judiciary Committee, cited recent court decisions and examples of dismissed whistleblower claims that they argued prevent citizens' efforts to report fraud.

"These problems are real and are costing American taxpayers money to litigate and, in some cases, denying the government recovery when they were defrauded," Grassley said in his testimony. "This is an unacceptable

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IN FOCUS

STATE DEVELOPMENTS IN THE 340B PROGRAM

Maine Considers Legislation to Maximize Use of 340B Program

Maine

Maine lawmakers are considering a far-reaching bill that would require state and local corrections agencies and the state health department to maximize access to discounted prescription drugs through the 340B program.

The measure, LD 2231, now before the legislature's joint Appropriations and Finance Committee, would require state prisons and county jails beginning in July 2009 to contract for inmate care exclusively with hospitals, clinics, and other entities that are eligible for and make reasonable efforts to participate in 340B.

State-funded managed care plans, the state Medicaid program MaineCare, state bulk purchasing initiatives, and targeted state programs for populations needing high-cost drugs would face the same deadline and requirement, but only if the state Department of Health and Human Services determines that doing so would yield cost savings.

"As a legislator, I'm looking at every possible way I can to save the state money in a way that doesn't wreck the services we now provide," says state Rep. Sharon Anglin Treat (D), the bill's sponsor. "The 340B program gives us an opportunity to continue to provide pharmacy services but at a much lower cost." Treat also serves as Executive Director of the National Legislative Association on Prescription Drug Prices and is a former state Senate majority leader.

Treat's bill touches on three of the thorniest issues before the current session of the legislature, now scheduled to end in mid-April: how to reduce a large and growing deficit in the two-year, \$6.3 billion state budget that runs through June 30, 2009, how to replace tens of millions of federal matching dollars that are expected to be lost as a result of new federal Medicaid rules, and whether a proposal to consolidate Maine's 15 county jails with the state prison system makes sense.

In November 2007, the state Revenue Forecasting Committee announced that tax collections, federal payments, and other state receipts for the 2008-09 biennium would fall \$95 million short of initial projections. In February it issued revised figures that nearly doubled the size of the two-year budget gap to \$190 million.

Much of the revenue shortfall is due to five new contro-

versial federal Medicaid rules that are expected to deprive Maine of \$45 million in federal health aid through the end of the biennium. On February 29, Maine, Maryland, New Jersey, and Oklahoma filed suit in the U.S. District Court for the District of Columbia seeking to quash one of the rules, which took effect on March 1 and is expected to reduce Maine's federal support for Medicaid case management services by \$16 million over two years.

Maine officials say they are confident that the courts will ultimately rule in their favor and that the disputed federal Medicaid funding eventually will be restored. In the meantime, however, they are desperately seeking ways to balance the budget by trimming state spending on Medicaid and other government services, including prisons and jails.

Even before the financial crisis erupted, Gov. John Baldacci (D) had begun negotiating with state lawmakers and local public safety officials over his proposal to merge Maine's county jails with the state corrections system. They recently agreed on draft legislation that would place the jails and prisons under the control of a new nine-member state board, whose duties would include developing a plan to cut costs through bulk purchases of commodities and services.

The Baldacci administration is continuing to study the bill, according to Jude Walsh, the governor's Special Assistant for Pharmacy Policy. She said the administration is chiefly interested in the measure's corrections and specialty drug provisions, noting that MaineCare already obtains prescription drug rebates in excess of 340B pricing through the state's participation in the Sovereign State Drug Consortium, the nation's first state-administered multi-state Medicaid drug purchasing pool.

"Given the federal cutbacks to Maine's Medicaid funding, the budget shortfall, and the need to find significant savings in the corrections and prison systems, I believe it borders on irresponsible not to explore what it would take to implement 340B pricing in Maine," Treat recently wrote in a memo to fellow lawmakers urging passage of her bill.

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IN FOCUS

STATE DEVELOPMENTS IN THE 340B PROGRAM

340B Legislation in Tennessee Would Benefit Satellite Facilities

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In 2003 while serving in the state Senate, Treat won passage of a resolution (SP 249/LD 771) directing the state health department to identify all possible ways Maine might expand its participation in the 340B program, including within state prisons and county jails. The department, however, never implemented the directive, Treat said. If it had, she noted, the state could have saved roughly \$650,000 “and that’s not even including the corrections provisions.”

The new bill’s stronger language, she said, “would impose a duty [on the health department] to say that it thinks there are no savings to be had” through more extensive participation in 340B.

To reap the benefits of 340B pricing, Maine’s prisons and jails would have to establish “some level of (inmate patient) case management” with 340B certified hospital or clinics, Treat said. Many, she continued, have already established such relationships to reduce prescription drug costs for inmates with expensive conditions such as AIDS.

But more generally, she said, state and local corrections officials have expressed reservations about her bill, noting for example that it would be hard for them to break existing contracts for the provision of prescription drugs to inmates that they have negotiated directly with drug manufacturers.

Treat countered, however, that such an argument should not hold sway given the state’s perilous financial condition. The corrections department “is not getting even the Medicaid price on prescription drugs now,” she said. “It is not getting the negotiating ability it would otherwise get” by embracing 340B pricing fully. “There are efficiencies here.”

The joint Appropriations and Finance Committee had not held a hearing on the bill as of early March. Nonetheless legislative leaders have been “very supportive,” according to Treat, noting that they waived a deadline that otherwise would have prevented her from filing the measure. If it moves forward, she said, it would most likely be as an amendment to critical supplemental budget legislation needed to address the state’s revenue shortfall.

Tennessee

A bipartisan group of Tennessee legislators is seeking to make it easier for the state’s Federally Qualified Health Cen-

ters (FQHCs) to dispense 340B discounted prescription drugs to patients at their satellite facilities via secure data, voice, and video computer links.

Companion bills SB 3122 and HB 4011 would allow registered nurses or certified pharmacy technicians at FQHC satellites to dispense prescriptions under the supervision of pharmacists at the centers’ main locations who oversee the process online. According to Christi Granstaff, Health Policy Director of the Tennessee Primary Care Association, the satellite centers would not stock drugs but would instead obtain filled prescriptions delivered to them by courier from the main centers. She said the bill would build on a recent series of state and federal grants to a consortium of Tennessee FQHCs to promote telemedicine and telepharmacy.

“This bill would be a big benefit to [the satellite centers’] patients in two ways,” Granstaff says. “First, they would not have to drive to another county to pick up their prescriptions. It takes the drive right out of the equation. Second, their only other option now is to get their prescription filled at a local pharmacy, but not with the 340B discount. If patients can pick up their prescriptions conveniently and at a discount, medication compliance is going to increase.”

State Rep. Joe Pitts (D), a co-sponsor of the House version of the bill and Chairman of the Board of Trustees of Memorial General Hospital District in Clarksville, Tenn., says it is rare for satellite centers to have a pharmacist on staff. State pharmacy laws currently prohibit the dispensing of prescription drugs unless a pharmacist is on site.

“There are a number of FQHCs with satellites in our state, and we’re looking for opportunities to use technology so that they are not duplicating services in every satellite they operate,” he says. “With this bill, we’re trying to make scarce resources go as far as possible.”

The bills are currently before the House Professional Occupations Subcommittee and the Senate General Welfare, Health, and Human Resources Committee. The current session of the legislature is expected to end in May.

House Mental Health Bill Includes Medicaid Drug Rebate Increase

Prospects for Final Passage Remain in Doubt

The U.S. House of Representatives passed legislation this month that would mean greater drugs rebates for the Medicaid program and possibly increased discounts for 340B program participants.

The mental health parity bill (HR 1424) passed in the House on March 5, 268-148, and will now go to the Senate. However, the House version faces extensive criticism from Republican lawmakers and President Bush, and it is uncertain if it will even make it to conference in the Senate. In order to become law, the Senate and the House need to iron out the differences between the two bills before it goes to the President for signature. The Administration has said it opposes any bill that expands mental health parity benefits beyond the Senate measure passed last year (S 558).

Some lawmakers argue the House measure is too far-reaching and oppose the offsets used to pay for them, including requiring pharmaceutical manufacturers to pay increased rebates to the Medicaid program. 340B and Medicaid stakeholders are particularly interested in Section 105 in the House bill that would increase the applicable Medicaid drug rebate for brand name drugs by five percentage points, from 15.1 percent to 20.1 percent.

The prices under the 340B program are calculated using the same discount mechanism that is used to determine Medicaid rebates. 340B ceiling prices for brand name drugs are currently the lower of average manufacturer price (AMP) less 15.1 percent or Medicaid best price with additional rebates if prices rise faster than inflation.

It is unclear whether 340B providers would benefit from the rebate increase. On the one hand, section 340B of the Public Health Service Act contains a provision that insulates the program from changes made to the Social Security Act, including the minimum rebate percentage applied to brand name drugs.

On the other hand, when the Office of Pharmacy Affairs was faced with a similar situation last year—whether to apply changes in AMP made to the Social Security Act to 340B price calculations—the agency reversed itself and decided to allow manufacturers to use the same AMP for both Medicaid rebate and 340B purposes (See February 2007's *Monitor*).

SNHPA Job Opportunity

Director of Pharmacy and Educational Services

Safety Net Hospitals for Pharmaceutical Access (SNHPA), formerly Public Hospital Pharmacy Coalition, is an organization of over 400 public and private non-profit hospitals and health systems that participate in the Public Health Service 340B drug discount program. SNHPA was formed to increase the affordability and accessibility of pharmaceutical care for the nation's low-income and underserved populations. SNHPA monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting safety net providers. SNHPA is dedicated to protecting the 340B program and creating new opportunities for member hospitals to save on pharmaceuticals.

About the Position:

SNHPA is hiring a pharmacist or other professional with experience in pharmacy operations to work full time for our Washington, D.C.-based non-profit hospital advocacy organization. Candidate must have experience in analyzing drug pricing data and with participating in the 340B drug discount program, pharmaceutical manufacturer patient assistance programs and, preferably, the Medicare Part D program. Experience at a disproportionate share hospital that participates in the 340B program is a significant plus. Public speaking experience and strong writing skills are also a plus.

Responsibilities:

- Provide pharmacy expertise to staff, members and outside organizations
- Take lead role in conducting and supervising various pricing analysis projects for organization
- Recruit new member hospitals and corporate partners to SNHPA
- Recruit exhibitors/sponsors for conferences
- Assume role in coordinating conferences, workshops, teleconferences, web casts, including developing agenda and recruiting speakers
- Liaison to other pharmacy organizations (ASHP, APhA, etc.), industry groups and the 340B Prime Vendor Program, Pharmacy Services Support Center and other 340B-related organizations
- Serve as lead contact with members and industry on patient assistance programs
- Provide support to SNHPA's regulatory and legislative team on pharmacy-related matters
- Draft letters, conference descriptions, policy pieces and other documents as needed
- Assume other duties that require pharmacy expertise
- Pharmacy degree preferable but not required

Pay is based on experience. Please send cover letter and resume to admin@safetynetrx.org or fax to SNHPA Administrator at 202-552-5868. Please state the starting date of your availability, salary requirements and how you became aware of this job.

Medicine for People Ends Eight-Year Run

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the California Attorney General's Office, Medpin reimbursed many California clinics last year for diabetic drugs and supplies as well as generic statin drugs. One of these was La Clinica de la Raza, which has locations in Alameda, Contra Costa and Solano Counties of California.

"Medpin has always made an effort to bring those drugs at either low cost or no cost," says Dolly Davar, La Clinica's Director of Pharmacy. "Medpin not being here will definitely affect us because we know that they were always negotiating on behalf of safety net clinics to ensure that we have some help in the form of products or money."

Medpin also served as a conduit to form working relationships among California's county indigent care systems, community clinics and faculty from the state's seven pharmacy schools.

In January 2002, Medpin began preparations for creating a statewide drug purchasing alliance of safety net providers for both 340B and non-340B drugs. Working with leaders from public hospitals, pharmacy schools, and community clinics, Medpin developed a plan for negotiating on behalf

of all California providers able to purchase through 340B, according to Duke.

Spearheaded by Duke's colleague Marice Ashe, the Safety Net Provider Purchasing Alliance was created in 2003. Despite extensive preparation, the Alliance never began purchasing, although it did continue through 2006 the work it had begun in educating California safety net providers about drug utilization management and pharmacy best practices.

And, with respect to public policy, Medpin helped develop and pass a state law allowing expanded use of the 340B program within community pharmacies and testified before California's legislature on various bills and ballot initiatives.

"Medpin has been a really important voice, particularly on prescription drugs," says Melissa Stafford Jones, President and CEO of the California Association of Public Hospitals and Health Systems, which represents all of the public hospitals in California and worked closely with

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12th Annual 340B Coalition Conference Improving Access to Pharmaceutical Care and Ensuring Compliance with Federal and State Laws



Omni Shoreham Hotel Washington, DC July 14-16, 2008

Conference registration is not yet available. To reserve a room at the Omni, call 1-800-843-6664. Be sure to mention the "340B Coalition Conference" to get our discounted rate of \$188 per night. Please contact Mike Hess at 202-552-5869 or mike.hess@safetynetrx.org with any questions.

For more information, go to www.340bconferences.org

OPA Pricing Verification Remains on Hold

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Human Services (HHS) Office of Inspector General (OIG). A July 2006 OIG report found one in seven purchases by 340B-covered entities was above the federally mandated ceiling price. The report called for greater penalty authority for OPA to enforce compliance with Section 340B of the Public Health Service Act, which echoed previous reports in recommending that HRSA officially compare manufacturer and government price calculations to detect discrepancies.

"I can recognize OPA's desire to abide by the court ruling, but we think they've gone way too far," says Ted Slafsky, Executive Director of Safety Net Hospitals for Pharmaceutical Access. "OPA should be able to help entities and the industry on pricing questions without revealing AMP data. If HRSA does not provide this service, it seriously undermines confidence in the government and the 340B program itself."

The prolonged injunction and continued delay of AMP publication is also disappointing to some 340B advocates who had hoped public AMP data would help providers verify that they are receiving accurate pharmaceutical prices, especially for generic drugs.

340B ceiling prices for brand-name drugs are the lower of AMP less 15.1 percent or Medicaid best price with an additional discount if prices rise faster than inflation. 340B ceiling prices for generic drugs are AMP less 11 percent. The DRA directed CMS to disclose AMPs to states on a monthly basis and to the public through a Web site updated quarterly.

Despite the fact that the government did not appeal the ruling by the February 19 deadline, the case is still moving forward. The lawsuit and injunction were also not changed because of an interim final rule CMS released this month that would redefine a "multiple source drug." A final decision in the case is not expected for a number of months.

John Rector, General Counsel and Senior Vice President of the National Community Pharmacists Association (NCPA), one of the plaintiffs in the case, says there was a lot of speculation that the government would appeal. "My view of the whole situation is that the government just does not seem to be in any hurry at all," he says.

Donna Yesner, a partner with the Washington D.C.-based law firm McKenna Long & Aldridge, speculates that the government did not appeal the case

because the limited injunction that the parties had worked out was not causing any disruption in the calculation of Medicaid rebates and 340B discounts or delaying pharmacies from being paid. Yesner took a lead role on behalf of a number of drug companies in convincing the court to continue allowing manufacturers to calculate Medicaid rebates and 340B discounts using the new AMP definition while the injunction is in place.

The National Association of Chain Drug Stores (NACDS) and the NCPA filed the lawsuit in November 2007 against HHS and CMS, arguing that the government's implementation of a provision in the DRA violated the Social Security Act by cutting Medicaid reimbursement to levels far below what Congress intended (See January's *Monitor*). The DRA rule would establish a new Medicaid payment formula for pharmacies that the drug-store industry argues could force up to 12,000 pharmacies to shut their doors.

The rule would also redefine AMP for brand-name and generic medications. The plaintiffs originally requested that a number of transactions now included in AMP should be excluded, including discounts to mail-order pharmacies—which would likely increase AMP and, consequently, raise 340B prices, according to some 340B providers and pharmaceutical industry analysts. However, the court decided to only halt the use of AMP for pharmacy reimbursement under the injunction. For now, the pharmaceutical industry and government will not have to alter their calculation methods.

"It would be very disruptive and just cause havoc if the court took it upon itself to define AMP," Yesner says. "I'm hoping that the court will not interfere with that, and if the court does decide to enjoin, I hope it would restore AMP to the way it was prior to the DRA."

The next step in the process, Rector says, is for the government to provide the plaintiffs with the administrative record—all of the documents that relate to the government's development of the DRA final rule—by March 31. After the record is provided, the plaintiffs would have at least 60 days to review the record and request any additional documents they think may be missing before the case moves forward and is addressed in a courtroom.

Rector says it is unclear how long the entire process will take. "It just depends on how responsive the government is," he says.

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AMP Lawsuit Injunction

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Mary Ellen Kleiman, Associate General Counsel at NACDS, the other plaintiff in the case, says NACDS has not been in discussions with the government about their choice not to appeal.

"The current posture of the case would be for [the case] to proceed to trial, but whether or not it will I can't say for certain," she says.

Whistleblower Legislation

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situation and needs to be clarified."

Whistleblower Tina Gonter testified that several of the amendments in question were critical to her case against the Hunt Valve Company, a subcontractor that makes valves for submarines. Her suit recovered \$13 million for the Navy. "Subcontractors who cheat the government are no different than prime contactors who cheat the government," she said.

Michael Hertz, Deputy Assistant Attorney General for the DOJ's Civil Division, said the DOJ is sympathetic to some of the proposed amendments and agrees with Grassley that recent court decisions have made it more difficult to administer the FCA. However, he said the DOJ does not support the bill in its current form, specifically the provision that would allow government employees to file suit under the FCA.

Some representatives from the pharmaceutical industry are also concerned about the possible far-reaching effects of the proposed changes on businesses that receive federal grants or reimbursement.

Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association that represents most brand name pharmaceutical manufacturers, said "The bill would impact all companies that do business with the government. As written, the act is not a technical corrections bill, but rather would needlessly and substantially alter the False Claims Act to expand the liability of businesses that operate lawfully with the government."

The Merck settlement is the seventh such agreement to include refunds for 340B providers. Previous 340B refunds have ranged from \$124,000 to \$10.6 million (See October 2007's *Monitor*).

SNHPA Job Opportunity

New Member Outreach and Grassroots Coordinator

The New Member Outreach and Grassroots Coordinator will serve as the liaison between SNHPA and non-member hospitals to engage them in SNHPA's legislative and regulatory advocacy activities and to educate them about SNHPA membership issues. This individual will report to SNHPA's Director of Government Relations and Executive Director and will assist in various lobbying activities and new member education and recruitment.

Job Description:

- Build and update database of non-member hospitals that are eligible to join SNHPA (approximately 300 hospitals)
- Coordinate SNHPA's grassroots and grassroots activities with respect to the non-member hospitals
- Mobilize non-member hospitals on key legislative and regulatory initiatives
- Assist SNHPA's advocacy team on general legislative work, especially regarding the development and implementation of SNHPA's legislative events such as Lobby Day, briefings, and other advocacy efforts
- Serve as a resource to non-members on matters involving SNHPA's membership services and advocacy agenda
- Forge relationships with non-members by arranging technical assistance calls with them, inviting them to SNHPA events, educating them on key policy issues, etc.
- Encourage non-member hospitals to join SNHPA
- Work with current members on advocacy efforts

Qualifications:

- At least two years of experience with health policy on Capitol Hill or at a trade association, lobbying shop or other advocacy organization
- Demonstrated evidence of building support for legislative and/or regulatory initiatives among target groups or industries
- Knowledge of federal policymaking and Congress
- Marketing and recruitment skills
- Bachelor's degree

Salary commensurate with experience. Full benefits package. Please send cover letter and resume to admin@safetynetrx.org or fax to SNHPA Administrator at 202-552-5856. Please state the starting date of your availability, your salary requirements and how you became aware of this job opening.

Medpin Closure

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Medpin on its initial project. "Medpin gave a home and a voice to an essential issue in terms of access—it is a loss not to have that voice and the energy."

During its eight-year span, Medpin also collaborated on projects and conferences with various groups such as Volunteers in Health Care/RxAssist, the 340B Coalition, Safety Net Hospitals for Pharmaceutical Access, and the Health Resources and Services Administration's Pharmacy Services Support Center.

"They provided a tremendous service, particularly for those on the West Coast," says Jim Mitchell, Director of the Office of Pharmacy Affairs. "They will be missed."

Despite Medpin's progress, Duke says that important work still remains to support indigent patients, especially because safety net providers often have a high turnover of staff. "Although we are pleased with the education and structural changes we were part of, when those staff leave, there is not a lot of institutional memory," she says. "Some of the things we've done need to be continued with new staff—it's an ongoing technical assistance issue."

To that end, Duke says an archival version of Medpin's Web site will remain online indefinitely and continue to provide information related to Medpin's past projects. "Much of the work that we did lives on through our Web site or through organizations that we partnered with," Duke says.

For Duke, her eight years of leading Medpin have been a fulfilling chapter in her history of work to reduce health disparities. Prior to Medpin, Duke served as Senior Staff Consultant for Health Policy at the California Senate Office of Research, as staff to the Senate Select Committee on AIDS, as a research faculty member of the University of California at San Francisco's Institute for Health Policy Studies, and as Manager of Scientific Affairs at the California Medical Association.

Duke also has graduate degrees in four disciplines including law and public health.

Duke cites her experience with the AIDS committee during the 1980s as an early foundation for her involvement in the project that became Medpin.

"Working on emerging medical and policy issues helped me realize that I enjoy working at a policy level while still making connections with the individual people affected by those issues," she says. "That was true during the 1980s with AIDS, and it's still true two decades years later at Medpin."

SNHPA Job Opportunity

Director of Legal and Regulatory Affairs

Safety Net Hospitals for Pharmaceutical Access (SNHPA) is an organization of over 400 public and private non-profit hospitals and health systems that participate in the 340B drug discount program. SNHPA was formed to increase the affordability and accessibility of pharmaceutical care for the nation's low-income and underserved populations. SNHPA monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting safety net providers. SNHPA is dedicated to protecting the 340B program and creating new opportunities for member hospitals to save on pharmaceuticals.

About the Position

SNHPA is recruiting a candidate to direct the legal and regulatory affairs for this 501(c)(6) nonprofit advocacy organization based in Washington, D.C. This position involves serving as in-house counsel and legal advisor to SNHPA on regulatory, legislative and compliance issues, including matters of statutory and regulatory interpretation, analysis of relevant case law, etc. The individual hired will report to SNHPA's President/General Counsel and Executive Director.

Responsibilities

- Participate with the President/General Counsel and Executive Director in interactions and advocacy efforts directed toward influencing federal policy with respect to the 340B drug discount program and related federal programs.
- Participate with SNHPA's legislative team in formulating and implementing legislative strategy, including drafting and commenting on proposed legislation and assisting, where appropriate, in lobbying efforts.
- Act as the organization's primary advisor on matters relating to litigation in administrative or judicial forums.
- Provide technical assistance to SNHPA members on matters relating to the 340B program and compliance with programmatic standards and requirements.
- Draft and review letters, memoranda, and other documents pertaining to questions of law and regulatory policy.
- Play a major role in planning, preparing for, and making presentations at conferences.
- Interact with the private counsel, federal and state government officials, Congressional staff, 340B Coalition members, SNHPA's Board of Directors, representatives of private industry, and other individuals and groups, as necessary to pursue and accomplish the objectives of the organization.

Candidates should have at least five years of legal experience and an understanding of pharmaceutical policy, Medicare, Medicaid and hospital issues. Please send cover letter and resume to admin@safetynetrx.org or fax to SNHPA Administrator at 202-552-5856. Please include the starting date of your availability, your salary requirements and how you became aware of this job opening.

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The Monitor

The Inside Source on the Public Health Service 340B Drug Discount Program

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